

REMARKS

Introductory Comments:

Claims 1, 2, 5-7, 10-15, 18, 21-29, 31, 33-35, 37, 39 and 40 were examined in the Office Action under reply and stand variously rejected under (1) 35 U.S.C. §112, first paragraph (claims 1, 2, 5-7, 10-15, 18, 21-29, 31, 33-35, 37, 39 and 40); and (2) 35 U.S.C §103(a) (claims 1, 2, 5, 6, 10-15, 18, 21-24, 26, 28, 29, 31, 33-35, 37, 39 and 40). These rejections are respectfully traversed as discussed more fully below.

Overview of the Above Amendments:

Claims 2-6, 8-11, 13, 14, 16-22, 30-34 and 36-40 have been cancelled herein and claims 1, 7, 12, 15, 29 and 35 have been amended to recite the invention with greater particularity. Specifically, independent claims 1, 12, 29 and 35 have been amended to incorporate recitations from claims 2, 10, 11, 18, 21, 22, 25, 31, 33, 34, 37, 39 and 40 and now recite that delivery is to skeletal muscle, that about 10^{10} to about 10^{15} rAAV virions are delivered and that the therapeutic effect is the formation of new blood vessels in the muscle to cause an increase in blood flow to the muscle. Additionally, claims 1 and 12 have been amended to incorporate recitations from claims 6 and 14 and recite that the angiogenic factor is VEGF. Dependent claims 7 and 15 have been amended to depend from non-cancelled claims. Support for the amendments can be found in the claims as originally filed, as well as throughout the specification.

The foregoing amendments are made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications hereof containing the cancelled or unamended claims.

Rejection Under 35 U.S.C. §112, First Paragraph:

Claims 1, 2, 5-7, 10-15, 18, 21-29, 31, 33-35, 37, 39 and 40 were rejected under

35 U.S.C. §112, first paragraph. The Examiner argues:

[T]he specification, while being enabling for directly administering rAAV virions comprising a gene encoding an angiogenic factor to the target muscle and expressing said angiogenic factor, wherein said expression of angiogenic factor results in the formations of new blood vessels to the muscles and for increasing blood flow to the muscle, does not reasonably provide enablement for expressing said angiogenic factor wherein said expression of said angiogenic factor results in any other therapeutic effect. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Office Action, pages 2-3, bridging paragraph. Applicants disagree and believe the claims as filed were indeed enabled throughout their scope. Nevertheless, solely in an effort to advance prosecution, the claims have been amended to recite that the therapeutic effect is “the formation of new blood vessels in the muscle to cause an increase in blood flow to the muscle.” This is the embodiment expressly stated by the Examiner to be enabled. Thus, this basis for rejection has been overcome and withdrawal thereof is respectfully requested.

Rejections Under 35 U.S.C. §103(a):

Claims 1, 5, 6, 10, 11, 29, 33, 34, 35, 39 and 40 were rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent Publication No. 2003/0096747 to Lue et al. (“Lue”), taken with U.S. Patent No. 6,004,797 to Colosi (“Colosi”). Applicants note that claims 2, 18 and 25 were not subject to this rejection. The independent claims subject to this rejection, namely 1, 29 and 35, have all been amended to include the recitations from non-rejected claims 2, 18 and 25. All of the remaining rejected claims either directly or ultimately depend from independent claims 1, 29 and 35. Thus, this basis for rejection has been overcome and withdrawal thereof is respectfully requested.

Claims 1, 2, 5, 6, 10-14, 18, 21, 23, 24, 26, 28, 29, 31, 33, 34, 35, 37, 39 and 40 were rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent Publication No. 2003/0148968 to Hammond et al. (“Hammond”) taken with Colosi. Claims 22 and 25 were not subject to this rejection. The recitations from claims 22 and 25 have been

inserted into all independent claims. Thus, this basis for rejection has also been overcome and withdrawal of the rejection is respectfully requested.

Claims 1, 5, 6, 10 and 11 were rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 6,589,782 to Neufeld et al. ("Neufeld"), taken in view of Colosi. Claims 2, 18 and 25 were not subject to this rejection and, as described above, the recitations from these claims have been incorporated into independent claim 1 from which claims 5, 6, 10 and 11 either directly or ultimately depend. Thus, this basis for rejection has also been overcome and withdrawal thereof is respectfully requested.

Claims 1, 2, 5-7, 10-15, 18, 21-24, 29, 31, 33 and 34 were rejected under §35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication No. 2003/0144200 to Baird et al. ("Baird") taken with Colosi. Claim 25 was not subject to this rejection. All independent claims now include the recitations from claim 25. Thus, this basis for rejection no longer applies and withdrawal of this rejection is respectfully requested.

Claims 1, 5, 6, 10-15, 21-29, 33-35, 39 and 40 were rejected under 35 U.S.C. §103(a) as being unpatentable over International Publication No. WO 02/02148 to Gao ("Gao") taken with Colosi. Applicants note claims 2 and 18 were not subject to this rejection and all independent claims have been amended to incorporate the recitations therefrom. Thus, this basis for rejection has been overcome and withdrawal thereof is respectfully requested.

Claims 12 and 25 were rejected under 35 U.S.C. §103(a) as being unpatentable over either Hammond or Baird, taken with Colosi and further in view of U.S. Patent No. 5,858,351 to Podsakoff et al. ("Podsakoff"). Claim 25 has been cancelled and claim 12 includes recitations from claims 14, 18, 21 and 22, none of which claims were subject to the rejection. Accordingly, this rejection no longer applies and should be withdrawn.


Based on the foregoing, all claims are believed to be free of the art.

CONCLUSION

Applicants respectfully submit that the claims define a patentable invention. Accordingly, a Notice of Allowance is believed in order and is respectfully requested. If the Examiner notes any further matters which he believes may be resolved by a telephone interview, he is encouraged to contact the undersigned by telephone at 650-493-3400.

Respectfully submitted,

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